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(54) Method and apparatus for vacuum treatment of an epidermal surface

(57) When treating an epidermal surface (surface of the skin) (3) with subatmospheric pressure supplied from a source (not shown) through a flexible tube (6), an applicator (4) is used consisting of a first, porous layer (7) of e.g. felt and a second, airtight layer (8) of e.g. plastic sheet material, the edge portions (9) of which extend beyond the first layer (7) and form a seal against the epidermal surface (3).

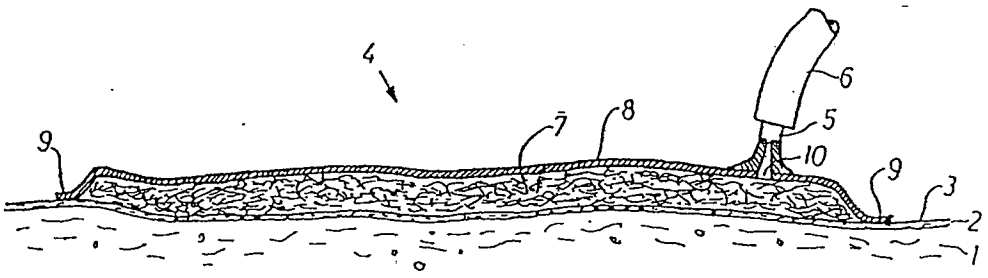

Fig.1

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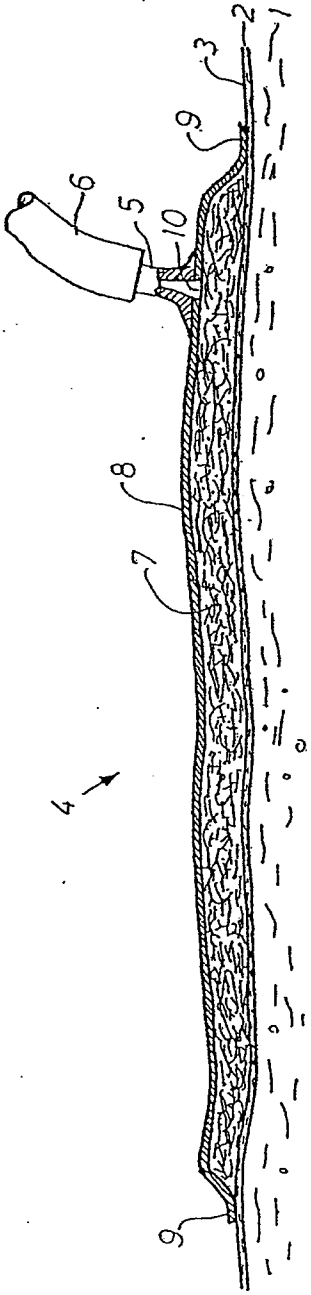

Fig.1

Fig.3

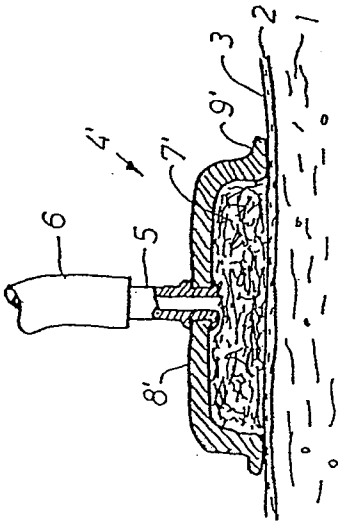

Fig.2

SPECIFICATION

Method and apparatus for vacuum treatment of an epidermal surface

The present invention relates to a method of applying subatmospheric pressure or partial vacuum to an epidermal surface.

Previously known methods of this kind usually involve placing the limb or other part of the body whose epidermal surface is to be treated with subatmospheric pressure, in a closed airtight chamber which is then evacuated, for example, by using a vacuum pump. To prevent the walls of the chamber from collapsing under the influence of atmospheric pressure, they must have considerable strength, especially in consideration of the subatmospheric pressure possibly being as low as 0.55 bar, corresponding to an external positive pressure on the chamber of almost half an atmosphere. Since the limb or part of the body in question is necessarily connected at one end to the body of the person in question, special measures must be taken to form an air-tight seal between that end of the vacuum chamber, through which the part of the body has been introduced, and that part itself. In cases where the subatmospheric pressure is to be applied to a large part of the body of the person in question, such as the part comprising the thorax and the abdominal cavity, the application of subatmospheric pressure to the outside of this part of the body may cause internal organs containing air or gases to be distended, and breathing may be disturbed.

Another disadvantage with the known methods is that the space within the vacuum chambers around the part of the body or limb may need to be of rather large volume, for which reason it may take a long time to evacuate them.

It is an object of the present invention to provide a method of the kind referred to free of the disadvantages mentioned above and being suitable for implementation by personnel without great technical ability with regard to operating apparatus.

According to the present invention there is provided a method of applying subatmospheric pressure to an epidermal surface, said method being of the kind comprising the formation of an airtight space outside said surface, said space being connected to a source of subatmospheric pressure activated to lower the pressure in said space, characterised in that said airtight space is formed by

(a) placing on and/or along said epidermal surface a first layer consisting of a porous and preferably flexible material of a kind comprising mutually communicating pores not losing the mutual communication when the material is subjected to compressive forces, and

(b) placing on the outside of said first layer and preferably also on the part of the epidermal surface closest thereto and not covered by said first layer, a second layer consisting of airtight and preferably flexible material.

Such a method is extremely easy to carry out, and provides partly the advantage that the force on the epidermal surface caused by the subatmospheric pressure is counterbalanced by the mechanical force produced by the same subatmospheric pressure acting on the second layer and hence on the epidermal surface. This force does, however, act on the epidermal surface solely on the relatively limited contact areas between the pores in the first layer, so that the epidermal surface facing the pores is fully influenced by the subatmospheric pressure. Experience has shown that the effect on the cutis and possibly underlying tissue is not inferior to the effect obtainable by using the previously known methods mentioned above.

The present invention also relates to an applicator for use in carrying out the method of the invention.

The invention will be further apparent from the following description with reference to the accompanying drawing in which:

Figure 1 is a sectional view showing a region of skin with an applicator according to a first embodiment placed thereon;

Figure 2 is a sectional view similar to Figure 1 through a skin region with an applicator according to a second embodiment; and

Figure 3 shows the use of a protective layer between the skin and the applicator on an enlarged scale.

The drawings shows diagrammatically a skin region consisting if subcutis 1 and epidermis 2, the latter having an external epidermal surface 3.

With the purpose of applying subatmospheric pressure to a part of the epidermal surface 3, there is on that surface placed a vacuum applicator 4, being connected to a source (not shown) of reduced pressure, which may be of a previously known type, through a tube-connecting stub 5 and a flexible tube 6.

In the embodiment shown in Figure 1, the vacuum applicator comprises a first layer 7, lying in contact with a part of the epidermal surface 3. The first layer 7 consists of porous material, the pores of which are interconnected and do not close upon application of a compressive force to the material. Such a material may for example be felt, which—as is well known—consists of mutually entangled fibres of wool or other natural or synthetic fibre. The vacuum applicator 4 further comprises a second layer 8, placed on top of (outside of) the first layer 7 and being so much larger than the latter in the extent of its area, that it is also in direct contact with the epidermal surface 3 with an edge portion 9. The second layer 8 is airtight and may, for

example, be constituted by a thin sheet of plastics or rubber. To make it possible to adapt the shape of the vacuum applicator 4 to the shape of the limb or body part in question, both the first layer 7 and the second layer 8 should be flexible, and this condition is fulfilled by using the materials mentioned.

In the second layer 8 there is formed a hole 10, and the tube-connecting stub 5 is secured to the second layer 8 in such a manner, such as by means of glue or cement, that the opening in the stub 5 communicates with the hole 10.

When the source (not shown) of subatmospheric pressure is connected to the flexible tube 6 the space between the epidermal surface 3 and the inside of the second layer 8 is evacuated through the stub 5 and the hole 10. If the first layer 7 were not present in this space, then the space would collapse immediately at the onset of the evacuation, and the second layer 8 would contact the epidermal surface in a fluid-tight manner, so that the subatmospheric pressure in the flexible tube 6 would be unable to reach the region of the epidermal surface covered by the vacuum applicator 4. The porous first layer 7 does, however, in a purely mechanical manner keep the second layer 8 spaced from the epidermal surface 3, for which reason the subatmospheric pressure between the fibres in the first layer 7 can propagate through the entire space between the epidermal surface 3 and the second layer 8, so that the part of the epidermal surface underlying the first layer 7 will in its entirety be subjected to subatmospheric pressure. At the same time, the epidermal surface 3 will be subjected to a mechanical force acting thereupon from the most adjacent fibres in the first layer 7, but since these fibers will only be in contact with a limited portion of the area of the epidermal surface 3, the major part of this surface will be subjected to the subatmospheric pressure.

Apart from the weight of the vacuum applicator 4, no net mechanical force is applied to the limb or body part comprising the epidermal surface 3, because the surface 3 is partly acted upon by an upwardly (as seen in Figure 1) directed force corresponding to the magnitude of the subatmospheric pressure multiplied by the area in question, while the epidermal surface 3 at the same time is acted upon by a downwardly directed force transmitted through the first layer 7, said downwardly directed force being caused by the effect of the very same subatmospheric pressure acting on the inside of the second layer 8, the area of which is substantially the same as the area of the epidermal surface 3 being acted upon. In spite of the apparently paradoxical situation involving the epidermal surface 3 simultaneously being acted upon by two equal and oppositely directed forces, the subatmospheric pressure in the first layer 7 will act upon the tissue below or behind the epidermal surface 3, since the subatmospheric pressure has access to the tissue through a rather large percentage of the surface, only the remaining part of the surface being acted upon by the mechanical force as directed downwards in Figure 1. Thus, practice has shown that by using a vacuum applicator constructed according to the principles illustrated in Figure 1 and explained in the foregoing, it is possible to obtain an effect on the cutis 1 2 and possibly the underlying tissue at least as effective as that obtainable using previously known apparatus for subjecting epidermal surfaces to subatmospheric pressures.

The first and second layers 7 and 8 respectively shown in Figure 1 may be extended in all directions and shaped in such a manner, that they for example form a bag-like or sleeve-like structure, that may be placed around a greater or smaller part of the body in question. In certain instances, however, it may be desirable to apply subatmospheric pressure to a very limited region of the epidermal surface, and in such cases it is possible to employ a vacuum applicator 4' as shown diagrammatically in Figure 2. Like the vacuum applicator 4 shown in Figure 1, the vacuum applicator 4' shown in Figure 2 also consists of a first layer 7' and a second layer 8'. Of these, the first layer 7' may—apart from the size—be identical to the first layer 7 shown in Figure 1, while the second layer 8' as shown in Figure 2 may be constituted by a vacuum cup, with which the tube-connecting stub 5 and with it the flexible tube 6 are connected in a known manner. The edge portion 9' of the vacuum cup 8' provides the requisite sealing effect against the epidermal surface 3.

In order to avoid the first layer 7 or 7' becoming dirty and to prevent the transmission of infectious matter from one person to another, it is possible as shown in Figure 3 to place a protective layer 11 between the epidermal surface 3 and the first layer 7 or 7'. The protective layer 11 should—of course—be made of a material capable of both transmitting the subatmospheric pressure and the mechanical force from the first layer 7 or 7', and to this end the protective layer 11 can suitably consist of a textile material, such as sheeting or the like, that may be disposable or laundered and/or sterilized.

The subatmospheric pressure being transmitted to the epidermal surface 3 by means of the vacuum applicator 4 or 4' may be of the order of magnitude 0.05 to 0.55 bar. The source of subatmospheric pressure (not shown) connected to the flexible tube 6 may be provided with means to adjust the subatmospheric pressure, possibly also means to vary this pressure in a preprogrammed manner, so that the subatmospheric pressure may be varied in a manner suitable for provid-

ing the desired effect on the epidermal region in question, possibly also the underlying tissue.

It will be appreciated that it is not intended to limit the invention to the above example only, many variations, such as might readily occur to one skilled in the art, being possible, without departing from the scope thereof as defined by the appended claims.

CLAIMS

1. a method of applying subatmospheric pressure to an epidermal surface, said method being of the kind comprising the formation of an airtight space outside said surface, said space being connected to a source of subatmospheric pressure activated to lower the pressure in said space, characterised in that said airtight space is formed by

(a) placing on and/or along said epidermal surface a first layer consisting of a porous and preferably flexible material of a kind comprising mutually communicating pores not losing the mutual communication when the material is subjected to compressive forces, and

(b) placing on the outside of said first layer and preferably also on the part of the epidermal surface closest thereto and not covered by said first layer, a second layer consisting of airtight and preferably flexible material.

2. A method according to claim 1, characterised by using as the first layer a layer of fibrous material.

3. A method according to claim 1 and claim 2 wherein said first layer is of felt.

4. A method according to claim 1, 2 or 3 characterised by using as the second layer a flexible sheet or foil.

5. A method according to claim 1 and claim 4 wherein said second layer is of plastics.

6. A method according to claim 1, 2 or 3 characterised by using as the second layer a vacuum cup, the internal space of which has substantially the same height as said first layer, and the peripheral edge of which is in contact with the epidermal surface around the first layer.

7. A method according to any one or any of the claims 1-6, characterised in that a protective layer of air-permeable material is placed on the epidermal surface prior to the first layer being placed thereon.

8. A method according to claim 7 wherein said protective layer is a textile material.

9. An applicator for carrying out the method according to any one or any of the claims 1-8, characterised by

(a) a first layer consisting of porous and preferably flexible material of the kind with mutually communicating pores not losing the mutual communication when the material is subjected to compressive forces, and

(b) a second layer adapted to be placed on the outside of the first layer and consisting of airtight and preferably flexible material, said second layer having a greater extent in area than said first layer and comprising means for connecting the space below or behind said second layer with a source of subatmospheric pressure.

10. An applicator according to claim 9, characterised in that said first layer consists of fibrous material.

11. An applicator according to claim 10 wherein said first layer is of felt.

12. An applicator according to claim 9, 10 or 11 characterised in that said second layer consists of flexible sheet material

13. An applicator according to claim 12 wherein said second layer is of plastics.

14. An applicator according to claim 9, 10 or 11 characterised in that said second layer consists of a vacuum cup, the internal space of which has substantially the same height as the first layer and the peripheral edge of which is adapted to be in contact with the epidermal surface around said first layer.

15. An applicator according to any one or any of the claims 9-14 characterised by a protective layer of air permeable material adapted to be placed between the epidermal surface and the first layer.

16. An applicator according to claim 15 wherein said protective layer is a textile material.

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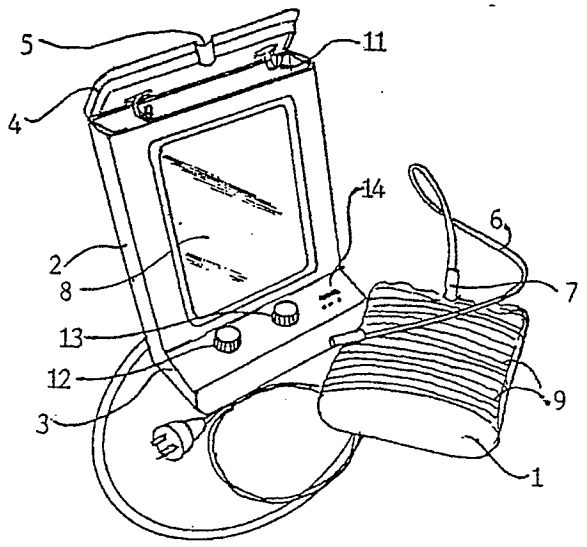
(54) Title: SUCTION SYSTEM FOR WOUND AND GASTRO-INTESTINAL DRAINAGE



(57) Abstract

A hollow chamber (2) adapted to receive a collapsible reservoir (1) for the collection of body fluids; an opening in said hollow chamber to facilitate the introduction and removal of a collapsible reservoir; means (4) to close and seal said reservoir such that a vacuum may be generated and maintained in said chamber; a first port in said chamber to facilitate evacuation thereof; means (8) to determine when a collapsible reservoir in the chamber is approaching a full state, and a second port (5) to facilitate a liquid conduit passing into the chamber.

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SUCTION SYSTEM FOR WOUND AND GASTRO-INTESTINAL DRAINAGE

The present invention relates to drainage of wounds and in particular to a system incorporating a suction device to facilitate such drainage.

The parting of flesh and bone occasioned by surgical intrusions into the body result in the secretion of low volumes of fluid into the wound even when the wound is correctly sutured or stabilised by other means in order to facilitate rapid healing. These fluids inhibit effective healing and consequently it has been the practice for many years to drain such fluids from the body during the healing process.

Such drainage is achieved by the introduction of a perforated cannula into the area of the wound, the cannula remaining in the wound and exiting through the skin to facilitate drainage for a number of days after closing of the wound.

In order to assist drainage of the wound a mild vacuum has been found desirable.

Traditionally the cannula is placed in communication with a vacuum via a tube which tube is also in communication with a reservoir for collection of drained fluid. There are presently two drainage systems in widespread use;the first utilising a disposable or re-usable bottle into which a vacuum is drawn. This bottle is then connected directly to the wound site by means of a length of plastic tubing terminating in the perforated cannula within the wound. This system however suffers from the disadvantage that a constant vacuum is not applied to the wound area. When the bottle

is initially placed in communication with the wound an adequate pre-determined vacuum is available in order to ensure drainage although as fluid drains into the bottle and after the bottle is exposed to the wound for some time period the available vacuum naturally decreases. International standards specify that it is not desirable to expose wounds to vacuums exceeding 180 millimetres of mercury (negative pressure) although in order to evacuate a bottle fully so that it will fill to capacity a much higher vacuum needs to be applied. Given that this starting vacuum is two or often three times that considered safe and acceptable displacement of vacuum by entering fluid means that the vacuum will slowly diminish through a safe level, then down to an unacceptable low level.

In order to prevent muscosa or tissue adhering to the perforated cannula and thereby impeding flow it is additionally desirable to provide an intermittent vacuum and it is difficult to achieve such result with the lastmentioned pre-charged bottle system.

The second system currently utilised involves an electrically operated pump capable of generating a vacuum and connected to the wound site via a collection jar or jars. This lastmentioned system can readily be programmed to provide an intermittent vacuum thus preventing muscosa or tissue adhering to the perforated cannula and allowing pooling of fluids in the wound site during the off-cycle ready for evacuation during the next on-cycle. Electrical suction units as lastmentioned however require the installation of

a bottle between the suction unit and the cannula and the changing of such bottle when filled. As patients may be suffering from communicable diseases such as AIDS the handling and changing of bottles by nursing staff is undesirable as the staff may come into contact with the evacuated fluids.

The present invention seeks to ameliorate one or more of the abovementioned disadvantages with existing suction systems or at least provide the consumer with an alternative system for wound drainage.

According to the present invention there is provided a hollow chamber adapted to receive a collapsible reservoir for the collection of fluids; an opening in said hollow chamber to facilitate the introduction and removal of a collapsible reservoir; means to close and seal said reservoir such that a vacuum may be generated and maintained in said chamber; a first port in said chamber to facilitate evacuation thereof; means to determine when a collapsible reservoir in the chamber is approaching a full state, and a second port to facilitate a liquid conduit passing into the chamber.

One embodiment of the present invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a perspective view of the principal components of a system in accordance with the present invention; and

Figure 2 is a frontal view from the top of an assembled system in accordance with the present invention.

Figure 1 depicts a collapsible plastic reservoir 1 and a moulded chamber 2. The moulded chamber includes a vacuum pump (not shown) in its base 3 and is provided with a hinged lid 4 to facilitate loading the chamber with the collapsible reservoir 1. The lid incorporates a seal along its interface with the main body of the chamber such that when the lid is a closed state a vacuum may be induced in the chamber 2. It will be noted that the lid 4 is notched at 5 in order to accommodate the plastic tube 6 and cannula connecting the reservoir to the wound site. It will be noted that the plastic tubing terminates in an enlarged joining piece 7 before it enters the reservoir, this enlarged joining piece serving a dual function. Firstly the enlarged joining piece, in this case of silicon, is resiliently deformable so as to conform to the shape of notch 5 thereby ensuring a good seal where the joining piece passes through the lid 4. The silicon joining piece additionally facilitates penetration by a needle and syringe in order that sampling or testing of fluids entering the reservoir may occur.

It will be noted that the chamber 2 has a transparent face portion 8 in order that the level in the reservoir may be observed without disturbing the system. It may further be observed that the reservoir itself is transparent and is provided with marked graduations 9 in order that the volume of fluid in the reservoir may be readily determined.

As may best be observed from figure 2 the upper portion of the welded borders of the reservoir are provided with apertures 10

intended to co-operate with hooks 11 on the underside of the lid 4 of the chamber 2 in order that the reservoir may be adequately supported within the chamber 2.

An alternate system not depicted would be to utilise press studs say male press studs on the inside of the chamber with female press studs on the external surface of the reservoir. If metal press studs were utilised then this system could be worked in with a "reservoir full" sensor. For example the press studs on the reservoir could be in electrical communication with short metal tapes extending down the inside of the bag. When the bag became full of liquid then the electrical resistance between each of the two said metal tapes would change thus enabling a sensor unit in the chamber and communicating with the reservoir through the press studs to determine the reservoir full state.

The vacuum pump (not shown) in the base 3 communicates with the chamber 2 via an inlet (not shown) adjacent the upper portion of the chamber. With such an inlet should a reservoir ever rupture fluid will not readily enter the pump unit. The base of the chamber preferably incorporates a moisture sensor which operates an alarm and pump cut off should a malfunction such as a rupture cause fluid to come into direct contact with the chamber. Control knobs 12 and 13 may be utilised to control the pump by selection of on/off or intermittent modes as well as regulating the vacuum. A bar graph 14 is provided in order that the level of vacuum may be accurately monitored. The L.E.D. depicted beneath the bar graph at 15 alert the operator as to specific faults or modes of the machine.

In this example three L.E.D.'s are provided the first being interconnected with a moisture sensor as above described in order

to protect against any leakage.

The second L.E.D. indicates that status of a switching device which turns the unit off when the reservoir reaches a full state. This switching device may take the form of a magnet implanted in the rear of the reservoir towards the top thereof which co-operates with a switching unit in the rear of the chamber when the reservoir is full and in an expanded state. The third sensor may warn as to a vacuum leakage as may occur when the wrong type of bag or no bag at all is inserted in the chamber. When any of the three lastmentioned L.E.D.'s illuminate an audible alarm may also be activated and the pump unit is switched off.

It is not essential for the present invention that the vacuum pump receive power from the mains and indeed it may be desirable in many circumstances that a battery back up be provided to ensure that the units operation was not dependent upon mains supply. In remote areas where access to mains power may be difficult and additionally in mobile applications such as ambulances and planes the unit could additionally be designed so as to operate from a battery or vehicles electrical system.

It should be appreciated that the present system eliminates any contact between drained fluid and the chamber 2 and associated pump and control equipment. The reservoir, canulae and plastic tubing may be disposed or removed to another location when full, again without the necessity of nursing staff coming into contact with fluid within the reservoir. The reservoir may

for example be connected to the patient (say in an operating theatre) prior to insertion into a vacuum chamber thus facilitating easy transport of the patient and reservoir (with cannula implanted in the patient) back to a ward having a suitable vacuum chamber.

Although the collapsible plastic reservoir is normally a sealed unit open only to the plastic tubing and cannula the chamber and vacuum unit should also be capable of accommodating a vented reservoir necessary to drain gastro intestinal wounds. Where gastro intestinal wounds are being drained a volume of gas may be discharged into the cannula along with fluids and consequently this gas needs to be evacuated from the resevoir in order that the reservoir may fill with fluid. This reservoir consequently requires a vent in order that the gases may pass into the chamber through the vacuum pump to atmosphere. A filter is required at the reservoir vent in such an embodiment.

It is desirable that all reservoirs should contain a non-return valve in order to prevent fluid returning along the inlet tubing and coming into contact with staff after the cannula or reservoir is removed.

Although the above described embodiment contains an integral vacuum pump it should be appreciated that this is not essential to the present invention and that the entire vacuum chamber assembly with sensors etc. may usefully be provided without a vacuum pump and adapted to plug into a central vacuum system usually present in modern hospitals.

It should be appreciated that further embodiments apart from that above described may be devised without departing from the scope and intendment of the present invention.

DATED this 30th day of January, 1987.

ROGER L.W. OSMOND

The claims defining the invention are as follows:

1. A hollow chamber adapted to receive a collapsible reservoir for the collection of fluids; an opening in said hollow chamber to facilitate the introduction and removal of a collapsible reservoir; means to close and seal said reservoir such that a vacuum may be generated and maintained in said chamber; a first port in said chamber to facilitate evacuation thereof; means to determine when a collapsible reservoir in the chamber is approaching a full state, and a second port to facilitate a liquid conduit passing into the chamber.

2. A chamber in accordance with claim 1 wherein the means to determine when a collapsible reservoir inside the chamber is approaching in full state is a transparent panel which allows observation of any collapsible reservoir within the chamber.

3. A chamber in accordance with any one of the preceding claims wherein there are additionally provided integrally with the chamber structure means for evacuating such chamber.

4. A chamber in accordance with claim 3 hereof wherein the integral evacuation mechanism is provided with a sensor and a variable control such that a range of pre-determined vacuums may be selected.

5. A chamber in accordance with any one of the preceding claims wherein the first (evacuation) port is located

adjacent an upper extremity of the chamber.

6. A chamber in accordance with any one of the preceding claims wherein the chamber includes adjacent a lower extremity a moisture sensor adapted to sense rupture of any reservoir within the chamber.

7. A chamber in accordance with any one of the preceding claims including a reservoir full sensor adapted to determine when a reservoir within the chamber reaches maximum fluid capacity such sensor having a sending capability adapted to trigger an alarm and/or stop a remote or integral vacuum pump.

8. A chamber in accordance with any one of the preceding claims further including a vacuum leakage sensor adapted to warn against vacuum leakage to atmosphere.

9. A chamber in accordance with any one of the preceding claims including a collapsible transparent reservoir having an inlet port adapted to project through the second (inlet) port of the chamber in such a manner that the exterior surface of the reservoir inlet port releasably seals against the internal surface of the chamber inlet port.

10. A chamber in accordance with claim 9 hereof wherein the inlet port for the reservoir is of resiliently deformable silicon projecting from the reservoir and the inlet port of the chamber is a notch in the chamber adjacent its opening adapted to receive said silicon

port and to sealingly captivate same when the opening in the chamber is in a closed state; the inlet port for the reservoir being adapted for releasable connection to tubing in order to facilitate communication with a wound site.

11. A chamber in accordance with claim 9 hereof wherein the inlet port for the reservoir extends into tubing terminating in a perforated cannula being adapted for insertion into living tissue.

12. A chamber in accordance with any one of claims 9 - 11 hereof wherein there are included means to positively locate the reservoir within the chamber.

13. A chamber in accordance with claim 12 hereof wherein the positive means comprise one or more hooks extending inwardly from an upper extremity of the chamber and adapted to pass through a corresponding hole in an upper extremity of the reservoir thereby suspending the reservoir within the chamber.

14. A chamber in accordance with claim 12 hereof wherein the positive means for locating the reservoir comprise one or more press studs on the interior of the chamber adjacent its upper extremity adapted to releasably lock onto a complementary press stud provided adjacent an upper extremity of the reservoir thereby suspending the reservoir within the chamber.

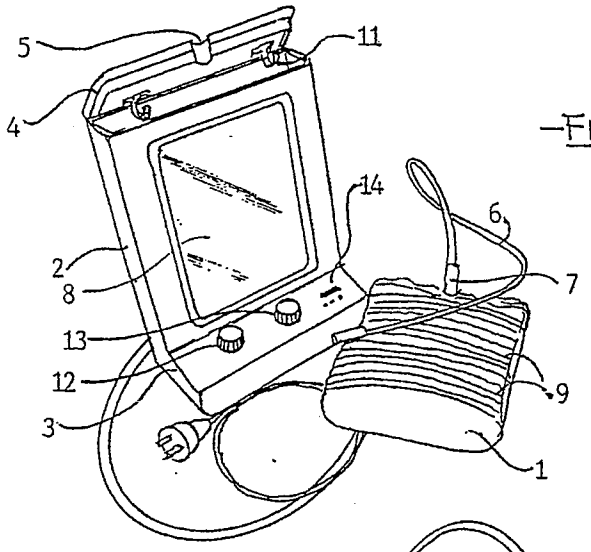
15. A collapsible reservoir for the containment of fluids

adapted for use in conjunction with a chamber in accordance with any one of the preceding claims wherein there is included a magnet adjacent an upper portion of the reservoir such magnet being adapted to trigger, vacuum, cut out and/or alarm devices contained within a surrounding chamber.

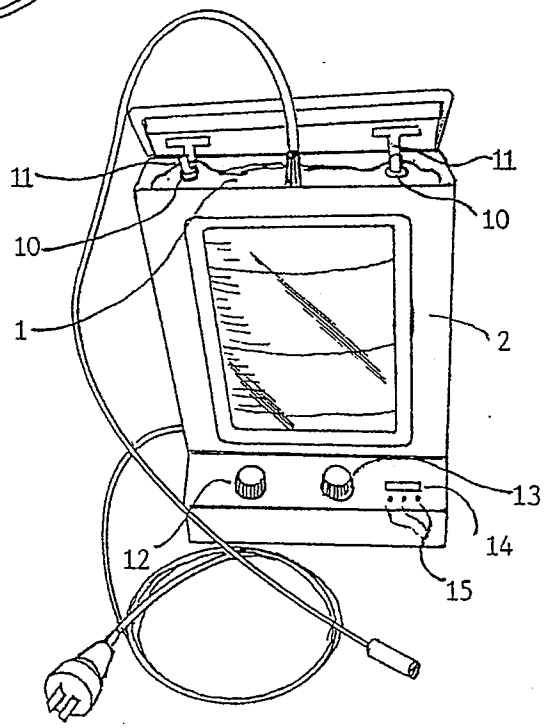
16. A collapsible reservoir adapted for use in conjunction with a chamber in accordance with any one of the preceding claims such reservoir including two outwardly directed press studs on its external surface adjacent its upper extremity each press stud being in electrical communication with a conductive wire or strip extending to the interior of the reservoir adjacent its upper extremity in such a manner that when the reservoir fills the lower extremity of each of the respective strips or wires will contact the fluid in the reservoir.

17. A chamber substantially as hereinbefore described with reference to the accompanying drawings.

18. A reservoir substantially as hereinbefore described with reference to the accompanying drawings.



-FIG. 1-



-FIG. 2-

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 87/00024

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl.[4] A61M 1/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC	A61M 1/00

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X,Y	DE,A, 1810801 (GERHARD) 4 June 1970 (04.06.70)	(1,2,5,8)
X	DE,A, 2127764 (BOVERI & CIE) 30 November 1972 (30.11.72)	(1-3,5)
X	EP,A, 82510 (LAUTERJUNG) 29 June 1983 (29.06.83)	(1,8)
Y	US,A, 3713444 (BRIDGEMAN) 30 January 1973 (30.01.73)	(1,5,7,8)
X	US,A, 3685517 (REYNOLDS et al) 22 August 1972 (22.08.72)	(1,5)
X,Y	US,A, 4111204 (HESSEL) 5 September 1978 (05.09.78)	(1,5,7)
X	US,A, 4392860 (HUCK et al) 12 July 1983 (12.07.83)	(1,2,3)
X	US,A, 3782384 (TIMMERMANS) 1 January 1974 (01.01.74)	(1,2,5)
Y	US,A, 3556101 (ECONOMOU) 19 January 1971 (19.01.71)	(1,8)
X	GB,A, 1400139 (MATHYS) 16 July 1975 (16.07.75)	(1,3,5)

* Special categories of cited documents: [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
27 April 1987 (27.04.87)	(05.05.87) 5 MAY 1987
International Searching Authority	**Signature of Authorized Officer**
Australian Patent Office	R Hallett R. HALLETT

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 87/00024

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Members		
DE 2127764	CH 531351		
EP 82510	DE 3150500 US 4522623	DK 5612/82	JP 58109061
US 3713444	US 3773211	US 3804089	
US 4392860	BE 881084 CH 634999 GB 2039745 NL 8000048	BR 8000188 DE 3000322 JP 55096159	CA 1133780 FR 2446113 MX 151334
US 3782384	DE 2106631 NL 7002440	FR 2078817	GB 1344369
US 3556101	DE 2005541	FR 2035196	
GB 1400139	BE 803897 IT 994643	CH 555183 JP 49058686	FR 2200743

END OF ANNEX

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(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB, GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.

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(54) Title: ABSORBENT DEVICES AND PRECURSORS THEREFOR

(57) Abstract

An absorbent device comprises an absorbent layer having an apertured contoured polymer film attached to one surface which surface is provided with a plurality of depressions which communicate directly with the apertures in the film. The device may be produced by separating the polymer film and a carrier material which have been formed into a laminate having impressed therein raised areas defining for example the strands of a net and depressed areas such that upon separation the depressed areas of the film remain attached together with associated portions of the attached absorbent, to the carrier, leaving the raised areas attached to the remainder of the absorbent.

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ABSORBENT DEVICES & PRECURSORS THEREFOR

The present invention relates to absorbent devices, to a laminate which is a precursor for an apertured and contoured film or net and to the film or net itself. The present invention also relates to processes for preparing absorbent devices the laminate and apertured film or net formed therefrom and to the use of the film or net as a body contacting layer in absorbent products such as dressings and hygienic devices.

Absorbent devices such as dressings and hygienic devices conventionally employ a water permeable film for their body contacting surface to act as a barrier between the body surface and the absorbent. A wound contacting layer, for example, for use in a dressing should also be conformable, non-adherent to the wound and to act as a means of preventing the healing wound incorporating the absorbent material into regenerating surface. One successful non-adherent absorbent wound dressing comprises a hydrophilic polyurethane foam bonded to a wound contacting layer comprising an elastomeric separator layer which is the polymer net.

Those dressing may be made by casting the net in a mould and then casting the foam on top of the net. This process involves many steps, expensive raw materials and imperfections in the mould may cause uneven net strand thickness and prevent clean release of the net from the mould. A further disadvantage is that the surface of the absorbent between the strands may be very close to the surface of the dressing hence presenting an opportunity for the absorbent to become incorporated in the healing wound or for the dressing to be more adherent than desirable under some circumstances.

The present invention accordingly provides an absorbent device comprising an absorbent layer and an apertured contoured polymer film attached to one surface which surface is provided with a plurality of depressions which communicate directly with the apertures in the film.

The absorbent device is preferably a wound dressing. I t has been found that such dressings allow for excellent healing of the wound, do not adhere significantly and easier to manufacture than prior art dressings.

The apertured contoured polymer film is a three-dimensional structure whose major surfaces are in spaced apart planes. The major surfaces of this structure are defined respectively by one surface of the raised portions of the contoured film and by the opposed surface of depressed portions of the film. The apertures in the film preferably all lie in the plane defining one of the major surfaces of the film and it is to this surface that the second layer is attached to the first layer. The apertures in the second layer register with voids formed by the depressions in the surface of the absorbent layer but the film material does not normally extend significantly into the voids.

The apertures in the film may be of a size and shape to give the apertured film the appearance of a net. For example, if the apertures are quadralaterals, the non-apertured part of the film will resemble the strands and junctures of a net. Circular or other non-rectilinear apertures may give the apertured film a different appearance. The apertured contoured film is preferably a net having strands and junctures formed from the polymer material.

A process has also now been found which makes the task of preparing a net or apertured contoured film suitable for use, for example as a wound contacting layer cheaper and simpler. The separator layers when used in dressings have been found to possess advantages over the separator layers previously used. These advantages occur as a result of the process used for their manufacture. The second or separator layer employed in the absorbent devices of the invention may be formed by laminating together a carrier material and a film which is to form the apertured or contoured film under conditions such that the laminate possesses an impressed pattern of raised areas, eg. defining the strands of a net. Between these areas or strands are defined membrane areas which are depressed areas in the film. Separation of the film from its carrier again by peeling them apart results in the membrane areas of the

film remaining adhered to the carrier material and the intersecting strands remaining, form the net. The laminate possessing these properties is novel. The production of the net via the laminate is simple, quick and not wasteful of raw materials.

The present invention also provides a laminate having impressed therein a pattern of raised areas with depressed areas therebetween said laminate comprising a carrier material and a film, wherein said film and material are attached to each other such as to permit, upon separation, the membrane areas of the film to remain attached to the carrier material.

In another aspect, the present invention provides a contoured apertured film which has been produced by the separation of a contoured polymer film and a carrier material which have been formed into a laminate having impressed therein a pattern of raised areas of the net and depressed areas said film and carrier material being attached to each other such that upon separation thereof the depressed areas of the contoured film.

In a preferred embodiment of the invention the laminate is impressed with a pattern of raised areas which will define the intersecting strands of a net.

The depressed areas define a membrane between the strands and upon separation of the carrier from the contoured film the membrane areas rupture to form the apertures of the net and the remaining, raised areas define the intersecting strands of the net.

A major advantage has been recognised in the preparation of dressings in which the net is adhered to an absorbent material. The absorbent material such as a foam may be cast onto the contoured film of the laminate before separation of the film and its carrier. In this method there is no risk of the foam exuding through the openings in the film since the film is not yet apertured. Separation of the carrier material from the foam coated film now not only removes the membrane areas but will also remove a little of the foam from between the strands which has adhered to the membrane areas. This results in deeper depressions in the foam surface between the strands so reducing the risk of the foam surface ever contacting the healing wound and also makes more surface of the foam available from absorbing body fluids.

The carrier material can be any deformable material. Aptly it can be a plastics film and preferably can be a thermoplastic film in which the polymer which forms the film can have a melting point

above that of the polymer forming the contoured film. Suitable films include pololefin and polyester films, for example low density polyethylene or a polyester film, available as Melinex (Trade mark) and polyamide materials such as Nylon films. Other deformable materials which are suitable include cellulosic products such as PVdC laquered cellulose and nitocellulose coated cellulose and uncoated products such as those sold under the trade name Cellophane and paper. The carrier material may be of any desirable thickness provided that, when laminated to the net-forming film, it is capable of being embossed and retaining the debossant. Aptly the carrier material will be at least 30μm thick. The thickness of the carrier material can be from 50 to 250μm, more suitably can be 100 to 175μm and is preferably 125 to 150μm.

The material for forming the apertured contoured film can be a polymer which flows under the influence of pressure and/or heat.

Aptly the film comprises an elastomer and preferably a thermoplastic elastomer.

Apt materials for use in forming the apertured contoured film include di- and tri-block copolymers such as those of hard block materials such as styrene

with softer block elastomeric materials such as isoprene or butadiene. Suitable materials in this group include block copolymer sold under the trade names KRATON and CARIFLEX.

Other apt elastomers for use in forming the apertured contoured film include hydrocarbons such as polyethylene or polyisobutadiene, polyester ether, polyester amides, polyurethanes and other copolymers such as ethylene-vinyl acetate copolymers or mixtures of such elastomers.

Suitable polyether-amide elastomers are disclosed in British Patent 1473972, French Patent Nos. 1444437 and 2178205 and United States Patent No. 3839245. An apt polyether-amide is known as Pebax 2533 SN00 available from ATO Chemical Products (UK) Limited. This polymer has a water content of approximately 55% when hydrated.

Suitable polyether-ester elastomers for use in the invention are known as Hytrel available from Du Pont (UK) Limited. An apt grade is known as Hytrel 4036.

Suitable polyurethane elastomers for use in the films used in the invention include relatively

non-hydrophilic linear polyester polyurethanes and linear polyether polyurethane elastomers for example those known as Estanes available from BF Goodrich (UK) Limited. Apt grades are Estanes 5701, 5702, 5714 and 58201.

Hydrophilic polyurethane elastomers, for use in the invention, can aptly have a water content when hydrated of at least 5% by weight. Suitably such elastomer may absorb upto 70% by weight, desirably from 10% to 40% by weight and preferably from 20% to 30% by weight, for example 25% by weight, water when hydrated. Suitable hydrophilic linear polyurethane elastomers for use in the invention are described in United Kingdom Patent No. 2093190.

Other suitable elastomeric acrylic polymers such as a copolymer of alkoxy alkyl acrylate or methacrylates, as for example those described in United Kingdom Patent Sepcification No. 1280631 and ethylene-acrylic acid or acrylic ester polymers such as those sold under the trade name PRIMACOR and LOTADUR.

Preferably the material for forming the apertured contoured film is a blend, suitably a blend of an elastomeric material with an incompatible more rigid polymeric material. Such blends may comprise the above

described elastomeric materials with a polyolefin such as polyethylene, polystyrene polycyclooctene or polypropylene.

Suitable blends include those of ethylene-vinyl acetate copolymers, polyurethane or polybutadiene with an incompatible polymers such as a polyolefin, for example polystyrene. Such blends are described for example in European Patent Specification Nos. 0141542 and 0046071 and in United Kingdom Patent Specification No. 2103537. Other preferred blends include those polyether-amides with high impact polystyrene, non-hydrophilic polyurethanes with hydrophilic polyurethanes, and polyurethane with linear low density polyethylene.

The ratio of elastomeric material to the other blend components is desirably chosen so that the elastomeric materials form the continuous phase of the blend and the other materials are in the discrete or discontinuous phase. Generally the elastomeric components will form at least 50% by weight of the blend. Aptly the blend will contain upto 90% by weight of the elastomeric components. Suitably the blend will contain between 55 and 85% of the elastomeric components. Certain ethylene polymers such as low density polyethylene and linear low density

polyethylene exhibit some elastic properties therefore may be considered to be part of the elastomeric components of blends containing such materials.

Preferred blends of an ethylene-vinyl acetate copolymer comprise from 10% to 90% by weight of ethylene-vinyl acetate copolymer more preferably 20 to 80% by weight of ethylene-vinyl acetate copolymer. Typical examples of such a blend comprises a blend of 40 parts ethylene-vinyl acetate copolymer and 60 parts high impact polystyrene, or a blend of about 25 parts ethylene-vinyl acetate copolymer, about 13 parts high impact polystyrene and about 60 parts linear low density polyethylene or a blend of from 40 to 90 parts by weight of ethylene-vinyl acetate copolymer and 60 to 10 parts by weight of high impact polystyrene.

The thickness of the film can be upto 250μm, suitably from 25 to 200μm, more suitably can be upto 150 to 175μm and is preferably from 30, more preferably from 60 to 150μm.

The films for forming the second layer may include filler materials or whitening agents such as calcium carbonate, titanium dioxide and the like. A suitable filled film is a polyethylene containing calcium carbonate.

The laminate can have membrane areas of any shape that can be produced by embossing. Such areas may be circular, elipsoidal, polygonal such as hexagonal or of more complex shape such as lobate, eg. trifoliate shape. Preferably the membrane areas are, quadralateral eg. diamond shaped or rectangular, for example they may be square. The membrane areas can have dimensions of from 0.02 to 4mm, more suitably can be from 0.05 to 2.5mm and preferably from 0.1 to 2mm. These dimensions are based on the side of a rectangle, other shaped areas will have areas and dimensions corresponding to major axes of the shape.

The depressed or membrane area can form at least 15% of the surface area of the laminate. Suitably the membrane area will form upto 80%, more suitably from 25 to 75% and preferably from 25 to 65% of the surface area of the laminate.

The laminate can have depressed areas corresponding to from 2 to 40 strands per cm of film surface, more suitably can have 3 to 40 strands per cm and preferably can have 4 to 24 strands per cm in both longitudinal and transverse directions.

The thickness of the embossed film ie. distance

between the planes of the major surfaces of the second layer can be from 0.1mm to 0.5mm and is preferably 0.15 to 0.4mm.

When the film is removed from the carrier material the film fractures around the perimeter of the membrane area to form apertures. The apertures in the film are equivalent area to the membrane areas described above. The strands or depressed areas in the apertured film retain their three dimensional character that is retain an arch shaped profile.

The laminate can be prepared by leading the carrier material and the polymer film together through the nip of two rollers. The first roller is a hard steel roller coated with a smooth rubber such as Hypolon (Trade mark). Generally, this roller is not heated. the roller contacts the film. The second roller is a steel roller which has an embossed pattern in its surface. A preferred embossed pattern can be of individual truncated square pyramids with troughs between the base edges of the pyramids. This roller can be heated. The film and carrier are laminated as they pass between the plain roller. The film and carrier passing between the plain roller and raised areas of the embossed roller form the membrane areas. The film and carrier deform into troughs between the

depressed areas to form the raised areas or strands. The film and carrier leave the nip as a laminate with an impressed pattern of strands with the membrane areas in between. The net or apertured film is formed by peeling apart the film and carrier. The film fractures around the laminated membranes so that the membrane areas of the net-forming film remain adhered to the carrier material and the intersecting strands form the net.

Thus, the adhesive strength between the carrier and the film in the membrane region has to be greater than that in the region of the strands or raised areas and the adhesive strength in the absorbent should be less than the adhesive strength between the carrier and the film in the membrane region.

The pattern of the impressed raised areas or strands and depressed areas or membranes can depend upon the pattern engraved on the surface of the roller. Unequal density of strands in either longitudinal or transverse directions may lead to rectangular holes in the net; likewise continuous parallel strands in one direction direction with staggered arrangement of strands in the other direction can lead to brickwork pattern; strands arranged at angles to each other can give a diamond pattern and different shaped

embossments, for example circular or hexagonal can lead circular or hexagonal apertures respectively. The engraved surface can contain mixed patterns or may contain plain areas where no pattern is impressed or laminate is formed.

In another aspect therefore, the present invention provides a process for the preparation of a laminate having a pattern of raised areas defing strands with depressed areas therebetween defining membrane areas and comprising a carrier material and a polymer film which can be separated after lamination such that the membrane area of the film remains attached to the carrier material and the strands form a contoured apertured film net which process comprises laminating the films together between a plain and embossed surface under the influence of heat and/or pressure.

In another aspect, the present invention provides a process for the preparation of a contoured apertured film or net which comprises separating the film and its carrier forming the laminate described hereinbefore.

If the apertured contoured film or net is to form the wound contacting layer of an absorbent dressing in which an absorbent material is attached to the net,

then it is advantageous to attach the absorbent to the film before this film is removed from the carrier material to form the apertured contoured film net. Removal of the carrier material provides an absorbent material having one surface attached to a net.

Accordingly in another aspect the present inventon comprises a laminate as hereinbefore described which has additionally an absorbent material attached to the surface of the polymer film remote from the carrier material.

Suitably the surface of the polymer film to which the absorbent is to be attached may be treated to enhance bonding. Such treatments can include a corone-discharge treatment of the film or the application of a suitable adhesive thereto.

The absorbent material employed in the absorbent layer can be any one of those conventionally used in absorbent dressings including gauze, wood pulp, cotton webs, rayon fibres and foams especially hydrophilic foams. Preferably the absorbent material is a foam. More preferably the absorbent layer comprises a conformable, hydrophilic foam. Apt foams may be made from polyurethane, carboxylated butadiene-styrene rubber, polyacrylate, polyester foams, hydrophilic

epoxy foams and hydrophilic polyurethane foams described in European Patent Application No. 299122 which are incorporated herein by cross-reference.

Favoured hydrophilic polymer foams are formed from hydrophilic polyurethane especially cross-linked hydrophilic polyurethane. Such hydrophilic polyurethanes will generally absorb at least 5% by weight of water when hydrated and aptly will absorb upto 300 or 400% of their weight of water when fully hydrated. Preferred foams include those described in European Patent Specification No. 299122 and known as Hypol foams made from Hypol hydrophilic isocyanate terminated prepolymers (Hypol is a trade mark and is available from W.R. Grace and Co). The prepolymers are mixed with water and coated onto the net-forming film of the laminate where foaming occurs. The foam is then cured. The carrier material may then be removed. Removal of the carrier material results in not only removal of the membrane areas of the film but also a small amount of foam attached to them. The recesses between the strands are noticeably deeper than observed previously which means that the absorbent surface is at greater distance from the wound surface and hence is less likely to become integrated with the healing wound.

Aptly the absorbent material can have a thickness of at least 0.5mm and suitably will have a thickness upto to 20mm. More suitably the absorbent will be 1 to 15mm preferably 2 to 10mm, for example 4mm, 6mm, or 8mm, thick.

If the absorbent material is other than a foam an adhesive may be used to adhere the absorbent to the film or laminate. Removal of the carrier film removes the membrane areas and cause cohesive failure in the absorbent material so a little absorbent is removed from the area between the strands as before.

In yet another aspect, the present invention provides a process for the preparation of a foam-coated laminate, said laminate having impressed therein a pattern of raised areas defining intersecting strands having membrane areas defined therebetween and comprising a carrier material and a contoured polymer film which can be separated after lamination such that the membrane areas of the film remain attached to the carrier material and form apertures in the film which process comprises laminating a polymeric film and carrier therefore together between a plain and embossed surface under the influence of heat and/or pressure forming a foam on the surface of the laminate and curing the foam.

In another aspect, the present invention comprises a process for preparing a wound dressing which comprises separating the carrier material from the foam-coated laminate described hereinbefore.

The absorbent material can contain topically effective medicament. Most suitably the medicament is an antibacterial agent. Preferably the antibacterial agent is a broad spectrum antibacterial agent such as silver salt such as silver suphadiazine, an acceptable iodine source such as polyvinyl pyrrolidone-iodine, chlorhexidine salts such as digluconate, diacetate, dihydrochloride or the like or quaternary antibacterial agents such as benzalkonium chloride.

The medicament can be present in amounts of at least 0.2% by weight of the dressing, and aptly upto 20% by weight of the dressing. More suitably from 0.3 to 10% by weight and preferably 0.5 to 5% by weight of the dressing of medicament may be incorporated.

In another type of dressing, the surface of the foam may have continuous moisture vapour transmitting conformable film over the surface opposed to the attached to the contoured apertured film or net. This further film may be used to regulate the moisture loss

from the wound area under the dressing and also to act as a bacterial barrier to prevent bacteria penetrating to the wound area.

The moisture vapour permeability of a film is expressed by its moisture transmission rate and can be determined as follows.

Discs of the material under test were clamped over Payne Permeability Cups (flanged metal cups) using sealing rings and screw clamps. The exposed surface area of the test sample is $10cm^2$. Each cup contains approximately 10ml of distilled water.

After weighing the cups are placed in a fan assisted electric oven which is maintained at $37\pm1°C$. The relative humidity within the oven is maintained at 10% by placing 1Kg of anhydrous 3-8 mesh calcium chloride on the floor of the oven.

The cups are removed after 24 hours, allowed to cool for 20 minutes and re-weighed. The moisture vapour transmission rate of the test material is calculated from the weight loss and expressed in units of grams of weight per square metre per 24 hours. The units for moisture vapour transmission rate will hereinafter be expressed as gsm.

Apt continuous films can have a moisture vapour transmission rate of greater than 300-^{2} 24h^{-1} at 37°C and 100% to 10% relative humidity difference. SUitably the moisture vapour transmission rate not normally be greater than 5000gm^{-2} 24h^{-1} at 37°C and 100% to 10% relative humidity difference. Preferably, the moisture vapour transmission rate will be greater than 500, more preferably at least 700 and most preferably at least 2000 gm^{-2} 24h^{-1} at 37°C and 100% to 10% relative humidity difference.

Suitable polymers for use as a continuous film include polyether or polyester polyurethane or blends of polyurethanes with incompatible polymers such as polyolefins, for example polystyrene and may include those materials described above for producing the contoured apertured film. Aptly the films will be at least 12.5 thick. Suitable films will be upto 50μm thick, favourably between 25 and 40μm thick.

Preferred polyurethane films are made from linear polyurethanes as hereinbefore described with respect to the wound facing layer. Favoured continuous films will be 12.5 micron to 37.5 micron thick. A preferred polyurethane for use in such thickness is Estane 5714F. A 25 micron thick film of Estane 5714F has a moisture

vapour transmission rate of approximately 1800gsm so that it may be employed to produce a moisture vapour transmission within the preferred range.

The outer layer can be a conformable polyurethane incompatible polymer blend film containing voids.

Suitable conformable polyurethane blend films are disclosed in United Kingdom Patent Application No. 8214250, now published as Application No. 2081721.

Apt conformable polyurethane blend film outer layers have a thickness 0.0125mm to 0.125mm. Such films can have a moisture vapour transmission rate of at least 500gsm and preferably at least 1000gsm.

A preferred polyurethane blend film comprises a blend of a linear polyurethane (60 parts by weight of Estane 580201 available from B.F. Goodrich) and a high impact polystyrene (40 part by weight of compound ref. 6MW available from R.H. Cole Limited). A favoured film of this composition has a thickness of 0.084mm and a moisture vapour transmission rate of 1660g/m^2/24 hours at 37.5°C at 100% to 10% relative humidity difference.

The continuous film can be applied by spraying a solution of the polymer forming the film onto the foam

surface.

This in other aspects the present invention provides a foam-coated laminate as hereinbefore described in which the foam layer is attached to a continuous moisture vapour permeable film and a low wound adherency dressing form from this laminate.

The invention also provides a process for making this laminate and the dressing made by said process.

The laminate which includes the absorbent layer may be made available as a dressing precursor with the hospital personnal preparing the dressing in situ tearing off the carrier material.

The wound dressing aspect of this invention may be in any convenient form through a dressing of generally rectangular or circular shape may be preferred.

Suitable sizes for rectangular pads are from 5cm x 5cm to 30cm x 30cm. An alterntive form is the form of an elongate strip which may be in the form of a roll.

Aptly absorbent devices of the invention,

including those having a continuous moisture vapour transmitting film over the absorbent layer will have a moisture vapour transmission rate of at least 300gsm, preferably at least 500gsm, more preferably more than 700gsm. The upper limit will be dictated by the moisture vapour transmission rate of the continuous film, if present. Absorptive devices, for example those suitable for use as wound dressings will have moisture vapour transmission rates of not more than 5000gsm more aptly not more than 3000gsm and preferably not more than 2000gsm.

It is desirable that the wound dressing aspects of this invention are sterile and are provided in bacteria impervious pouches. Such a packaged forms may be prepared under aseptic conditions from sterile components or may be sterilised after packing by a conventional procedure such as heat sterilisation or ethylene oxide or gamma irradiation.

The wound dressings of the present invention have improved adherency properties when compared with conventional foam-net dressings. We have observed that dressings in accordance with the invention may require only half the force required to remove a conventional foam-net dressing from equivalent wounds.

The absorbent devices of the invention may also be employed for use as first aid dressings. Additionally they may be employed as sanitary napkins and baby diapers.

Example 1

A polymer blend containing 90 parts by weight of ethylene-vinyl acetate copolymer (containing 28% vinyl acetate) and 10 parts by weight of high impact polystyrene and 4% by weight of the polymers of titanium dioxide was formed by mixing the polymers in a heated blade mixer, forming into a sheet and then granulating. The granules were formed into a film of thickness 125μm by extrusion through the nip of a two roller casting unit. The film was taken upto a roll. This was the net-forming film.

The polymer blend film and carrier of low density polyethylene, of thickness 150μm, were lead, in contact between the nip of two rollers. The first roller comprises a hard rubber coated roller devoid of pattern and at room temperature. This roller was in direct contact with the polymer blend film. The second roller comprised a heated steel roller engraved with a pattern of raised discrete truncated square pyramids. The

roller had a pattern of 4 x 4 raised areas per sq cm to truncated top of which had an area of 2 x 2mm. This roller contacted the polyethylene film. The influence of the heat and pressure produced a laminate of the two films which had impressed into it the pattern on the roller. THe pattern comprised intersecting strands defining square membrane areas between them, neither film was apertured on leaving the nip between the rollers. The laminate may be stored on a roll.

Preparation of the Net

The net may be formed in the polymer blend film by separating it from the carrier. The membrane areas of the polymer blend film remain adhered to the polyethylene film. The net had approximately 16 apertures per sq cm each of which had an area of approximately 4 sq mm.

Example 2

A laminate formed by a similar method to that described in Example 1 was taken and onto the polymer blend surface was cast a hydrophilic polyurethane foam forming mixture. The mixture was formed by mixing Hypol FHP2002 and Brij 72 in the ratio 1:2.25 and coated via a fish tail die on to the laminate by means

of a knife over roller coating head set at a gap of 1mm. The cast foam was dried by passage through an air circulating oven at a temperature of 50°C for 5 minutes. The polyethylene film was peeled from the polymer blend film leaving the now apertured polymer blend film adhered to the foam. The material can be used as an absorbent wound dressing in which the apertured polymer blend film forms the contacting layer.

Example 3

A polyethylene film-polymer blend film-foam laminate was prepared as described in Example 2. A solution containing 2% by weight of a polyurethane (Estane 5714F) in a mixture of tetrahydrofuran and acetone as solvent was hand sprayed on to the foam surface using an air spray unit and dried by passage through a air circulating oven heated to a temperature of 70°C.

The polyurethane coating was observed to be continuous and had a weight per unit area of 30 grams per square metre.

The polyethylene film was peeled from the polymer blnd film to form the apertures. The film-foam-film

laminate could be cut into pieces suitable for use as a absorbent wound dressing and packaged in a bacteria proof pack and sterilised in a conventional manner, for example by gamma irradiation.

Example 4

A laminate was formed in a similar manner to that described in Example 1. The net-forming film of the laminate was coated with a foam formed in the following way, polyethylene glycol nonyl phenyl ether (Anterox CO-520, 1 mole) was mixed with an aliphatic isocyanate (Desmodur N 100, 3 moles) and dibutyl tin di laurate as catatlyst in a wide necked jar at a temperature to maintain the components fluid. The reaction product was used to form a foam by mixing with 10% by weight of water. The foaming mixture while fluid was cast onto the net-forming film by the method described in Example 2. The preparation of the foam is described as Example 17 of European Patent Application No. 299122.

Example 5

A control wound dressing was manufactured according to the method described in European Patent Specification No. 059049 except that the polyurethane foam was that described in Example 17 of European

Patent Specification No. 299122.

The foam was cast onto an Estane net, which itself had been cast onto a polypropylene carrier. A 20 grams per square metre Estane film was then applied to the top surface of the foam and once the foam had cured the carrier was removed.

The thus formed dressing, after sterilisation was applied to a partial thickness wound and held in place by adhesive tape for four days.

A dressing as described in Example 4 was placed on a similar partial thickness wound and also held in place by adhesive tape for four days.

The dressing was removed by first removing the adhesive tapes whilst holding the dressing against the body. The dressings were then removed using a Nene tensile testing machine to measure the force required to break the bond between the dressing and the healing wound surface.

In both cases the dressings were removed cleanly leaving no residues on the healing wound surface. The force required to remove the Control dressing measured 97.68 on the testing machine whereas that required for removing the dressing of the invention was only 40.40.

CLAIMS

1. An absorbent device comprising an absorbent layer having an apertured contoured polymer film attached to one surface which surface is provided with a plurality of depressions which communicate directly with the apertures in the film.

2. An absorbent device comprising an absorbent layer and an apertured contoured polymer film attached thereto which apertured contoured polymer film has been produced by the separation of a contoured polymer film and a carrier material which have been formed into a laminate having impressed therein a pattern of raised areas and depressed areas therebetween, said film and carrier being attached to each other such that upon separation the depressed areas of the film remain adhered to the carrier thereby forming apertures in the contoured film.

3. A device as claimed in claim 1 or claim 2 wherein the contoured apertured film is a net.

4. A device as claimed in any one of the preceding claims wherein the polymer film comprises an elastomer.

5. A device claimed in claim 4 wherein the elastomer is a thermoplastic elastomer.

6. A device as claimed in any one of the preceding claims wherein the film polymer is a polymer blend.

7. A device as claimed in any one of the preceding claims wherein the polymer blend is a blend of an elastomer and a more rigid polymer.

8. A device as claimed in claim 6 or claim 7 wherein the elastomer comprises the continuous phase of the blend.

9. A device according to any one of claims 4 to 8 wherein the elastomer is an ethylene-vinyl acetate copolymer, a polyurethane or a polyether polyamide.

10. A device as claimed in any one of the preceding claims wherein the film polymer comprises a polyolefin.

11. A device as claimed in any one of the preceding claims comprising a further layer of a continuous moisture vapour permeable film attached to the surface of the absorbent layer opposed to that attached to the second layer.

12. A device as claimed in claim 10 wherein the further layer has a moisture vapour transmission rate of at least 300gsm.

13. A device as claimed in claim 11 or claim 12 wherein the further layer has a moisture vapour transmission rate of not more than 5000gsm.

14. A device as claimed in any one of claims 11 to 13 wherein the moisture vapour permeable film is made of an elastomeric material.

15. A device as claimed in claim 14 wherein the elastomeric material comprises a polyurethane, an ethylene-vinyl acetate copolymer or a polyether-polyester.

16. A device as claimed in any one of the previous claims wherein the absorbent material is a foam.

17. A device as claimed in claim 16 wherein the foam is a polyurethane foam.

18. A device as claimed in claim 17 wherein the polyurethane is a hydrophilic polyurethane.

19. A device as claimed in any one of the preceding claims having a moisture vapour transmission rate of at least 300gsm.

20. A device as claimed in any one of the preceding claims having a moisture vapour transmission rate of upto 2000gsm.

21. A device as claimed in any one of the preceding claims in the form of a wound dressing.

22. A device as claimed in any one of the preceding claims in the form of a sanitary towel or diaper.

23. A net for use as a wound contacting layer for a wound dressing formed by separation of a contoured polymer film and a carrier material which have been formed into a laminate having impressed therein a pattern of raised areas defining intersecting strands and depressed areas defining membranes between the strands, said film and carrier being adhered to each other such that upon separation the membrane areas of the contoured film adhere to the carrier material and the raised areas form the strands of the net.

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 90/00398

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[5]: A 61 F 13/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[5]	A 61 F, B 29 C

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	EP, A, 0059049 (SMITH & NEPHEW) 1 September 1982 see figures 2,3; pages 32-38	1,3-5,8,9, 11-22
Y	--	2,23
Y	EP, A, 0010439 (GRAIN PROCESSING CO.) 30 April 1980	2,23
	--	
X	EP, A, 0050514 (SMITH AND NEPHEW) 28 April 1982 see figure 3; claim 6	1,3-5,8
	--	
A	EP, A, 0259003 (EL PASO PRODUCTS CO.) 9 March 1988	1
	--------	

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
19th July 1990	23.08.90
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	Natalie Weinberg

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9000398

SA 35490

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 09/08/90
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A- 0059049	01-09-82	AU-B- 552887	26-06-86
		AU-A- 8037582	19-08-82
		CA-A- 1174447	18-09-84
		EP-A,B 0059048	01-09-82
		GB-A,B 2093702	08-09-82
		GB-A,B 2093703	08-09-82
		JP-A- 57153644	22-09-82
		US-A- 4860737	29-08-89
		US-A- 4753231	28-06-88
EP-A- 0010439	30-04-80	US-A- 4260443	07-04-81
EP-A- 0050514	28-04-82	AT-T- E8462	15-08-84
EP-A- 0259003	09-03-88	JP-A- 63041543	22-02-88
		US-A- 4815714	28-03-89
		US-A- 4778634	18-10-88

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